**GOVERNMENT OF INDIA**
**MINISTRY OF CHEMICALS AND FERTILIZERS**
**DEPARTMENT OF PHARMACEUTICALS**

LOK SABHA
UNSTARRED QUESTION No. 1042
TO BE ANSWERED ON THE 3rd December, 2021

**License to Pharma Companies**

**†1042. DR. RAM SHANKAR KATHERIA:**

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether several states are issuing licenses to pharmaceutical companies at their own level for manufacturing medicines while it is compulsory to obtain approval from the Union Government for every new medicine;
(b) if so, whether the Union Government has taken note of the matter; and
(c) if so, the details of the action taken by the Union Government in this regard and if not, the reasons therefor;
(d) whether any action has been taken against any institutes by the Union Government during last five years which has manufactured and distributed fixed dose combination medicines without its approval and if so, the details thereof, State-wise; and
(e) whether any such scheme under which the manufacturing and distribution of fixed dose combination medicines can be checked is under implementation and if so, the details thereof and if not, the reasons therefor?

**ANSWER**

**MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS**
**(Dr. MANSUKH MANDAVIYA)**

(a) to (c): The manufacture, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments.

Under the said Rules, permission is required for manufacture of any New Drug from Central Drugs Standard Control Organisation (CDSCO) before obtaining manufacturing license for the New Drug from the concerned State Licensing Authority.

Some cases of grant of manufacturing license of new drugs including Fixed Dose Combinations (FDCs) falling under the purview of the then Rule 122E of the Drugs & Cosmetics Rules, 1945 by some of the State Licensing Authorities (SLAs) without due approval of the Drugs Controller General (India) [DCG (I)] came to the notice of the Government.

Apart from issuing repeated statutory directions under Section 33P of the Drugs & Cosmetics Act, 1940 to the State Governments in this regard, the Central Government

constituted an Expert Committee under the chairmanship of Prof C.K. Kokate to examine the safety and efficacy of such FDCs.

Based on the recommendations of the Prof. C. K. Kokate Expert Committee, the Central Government prohibited 344 FDCs vide notification dated 10.03.2016. Further, the Central Government had also prohibited 5 FDCs vide notification dated 08.06.2017.

However, with respect to the said 344 FDCs, several writ petitions were filed in different High Courts across the country challenging the ban of the FDCs. After that, the High Court of Delhi vide its order dated 01.12.2016 quashed the said notification. The Union of India challenged the said order of Delhi High Court before the Supreme Court by way of filing Special Leave Petition (SLP). Further, 20 cases against 5 FDCs prohibited on 08.06.2017 which were pending before various High Courts across the country, were also transferred to Hon'ble Supreme Court. Hon'ble Supreme Court vide its order dated 15.12.2017 directed that an analysis be made in greater depth and these cases of (344+5) FDCs should go to the Drugs Technical Advisory Board (DTAB) and/or a Sub-Committee formed by the DTAB for the purpose of having a relook into these cases.

Accordingly, a Sub-Committee of DTAB was constituted which after providing hearing to all the petitioners/appellants, submitted its report to DTAB which was accepted by DTAB.

Based on the recommendations of DTAB, the Central Government vide notifications dated 07.09.2018 prohibited 328 FDCs for manufacture, sale or distribution as there was no therapeutic justification for these FDCs and they could involve risk to human beings. The Government also restricted 06 FDCs for manufacture, sale or distribution with certain conditions vide notifications issued on the same date. However, various firms/stakeholders have filed writ petitions in various High Courts across the country including the Hon'ble Supreme Court against the said notifications dated 07.09.2018.

Further, based on the recommendations of DTAB, the Central Government vide notifications dated 11.01.2019 prohibited 80 FDCs for manufacture, sale or distribution as there was no therapeutic justification for these FDCs and they could involve risk to human beings. These 80 FDCs were part of the list of 294 FDCs identified in year 2007, which were earlier subjudice in Hon'ble High Court of Madras.

**(d) to (e):** 68 cases of unapproved FDCs licensed by State Licensing Authorities (SLAs) considered as New Drugs, have been reported during the year 2017 to 2021 (till date). In all such cases, the office of Drug Controller General of India (DCGI) took up the matter with respective SLAs and written to them for taking necessary action against such FDCs as per Drugs & Cosmetics Act 1940 and Rules made there under. The State/UT-wise and year wise details of these 68 cases is **annexed**. Further, the state Drugs Controllers have also been instructed from time to time in the Drug Consultative Committee meetings to ensure that new drugs and FDC are not permitted without approval from the office of DCGI.

**ANNEXURE**

**Annexure referred to in reply to Lok Sabha UNSTARRED QUESTION. No. 1042 dated 03.12.2021.**

| Name of the State | No. of FDC for which licenses were granted by SLAs without prior approval of DCG(I) |
|---|---|
| Uttarakhand | 16 |
| Maharashtra | 11 |
| Daman & Diu | 3 |
| Himachal Pradesh | 9 |
| Tamilnadu | 2 |
| West Bengal | 1 |
| Karnataka | 3 |
| Gujarat | 3 |
| Sikkim | 9 |
| Jammu | 1 |
| Uttar Pradesh | 3 |
| Bihar | 1 |
| Telangana | 2 |
| Puducherry | 3 |
| Assam | 1 |
| **Total** | **68** |

**Year wise details**

| Year | Number of cases |
|---|---|
| 2017 | 21 |
| 2018 | 08 |
| 2019 | 17 |
| 2020 | 14 |
| 2021 | 8 |
| **Total** | **68** |

*****